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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,483	08/02/2001	Steven Finkbeiner	UCAL161DIV	7273

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,483	FINKBEINER, STEVEN	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-24 and 28-30* is/are pending in the application.

4a) Of the above claim(s) *14-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 20, 2003 in response to the Office Action of May 20, 2003 is acknowledged and has been entered. Claims 10-13 and 28-30 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The office acknowledges the amendment to the specification updating all parent priority applications in the first line of the specification.

Claim Objections

The objection of claim 10 is withdrawn in view of Applicant's amendment to the claim.

Claim Rejections - 35 USC § 112

The rejection of claims 10-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment to the claims.

The rejection of claims 10-13 and newly added claims 28-30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** fore reasons of record.

Applicant's arguments have been fully considered but fail to persuade. The issues discussed during the interview on October 8, 2003 were that neither the specification not the art has established that antibody binding to the polyglutamine expansion region of Huntington protein occurs in the same region that binds the unknown and undisclosed cellular receptor.

Applicants have cited the South et al. paper as providing evidence that the interaction of antibody that recognizes the GPIb domain of the vWF can be used to screen for peptide inhibitors that inhibit the binding between vEF-GPIb binding. The critical difference between the cited paper and the instant specification is that in the South et al. paper the authors actually knew that the antibody binds to the GPIb domain that recognizes the vWF. In the instant specification the antibody binds to the polyglutamine expansion protein yet there is no correlation provided that the region to which the antibody binds is the same region that is responsible for the binding the polyglutamine expansion protein to the normal cellular receptor.

Applicants have cited the Kaji et al. paper as providing evidence that the interaction of an antibody that inhibits the chemotactic activity of monocyte chemoattractant protein (MCP-1) can be used to screen for peptide motifs that are inhibitors of the interaction. The critical difference between the cited Kaji et al. paper and the instant specification is that in the cited paper the authors have associated an activity that is inhibited with the antibody. In the instant specification the examples provided teach a method of how to generate an antibody to the polyglutamine expansion protein and comparing the binding of the antibodies to an antibody, 1C2, from the prior art. The specification has not provided any evidence that the antibodies prevent the binding of the Huntington protein to the undknown and undisclosed putative cellular receptor.

Therefore, Applicant arguments that the disclosed antibody can serve as a surrogate receptor is not convincing.

The preamble of the claim is directed to identifying compounds capable of modulating the interaction between mutant Huntington protein and its (cellular) targets. Yet the method steps outlined in the claim will only measure the interaction between mutant Huntington protein and an antibody, antibodies are not the normal cellular target of the Huntington protein.

The specification does not teach a method of screening agents that "is capable" of modulating the interaction of mutant Huntington protein with the normal cellular target of the Huntington protein. The method steps merely indicate that the agent may interfere with the antibody binding to the polyglutamine expansion protein, yet the methods cannot distinguish whether the agent binds to the antibody or the polyglutamine containing protein.

The prior art teaches that the mAB 1C2 specifically recognizes polyglutamine expansions in soluble Huntington. However, the antibody does not recognize insoluble high molecular weight polyglutamine expansions. Indicating that 1C2 recognizes an elongated polyglutamine tract but not when in an a fibrillar conformation (see Heiser et al. IDS Paper No. 6, page 6740). . The reference teaches a screening assay that interferes with the self aggregation of Huntington which is thought to be the cause of the neurodegenerative disease. The reference indicates that 1C2 (monoclonal) antibody, HD1 (polyclonal) antibody as well as Congo Red are able to prevent the Huntington protein from aggregating (see Heiser et al. IDS Paper No. 6, page 6741). Applicant's arguments to the 1C2 antibody used in the Heiser et al. reference is simply that the specific antibodies set out in Example 1 and designated 1F11E5, 4H7H7, 3A2D3, 4F1B5, 3C4A6 and 3B5H10 have different binding affinity to the polyglutamine expansion protein than

the 1C2 antibody. That the antibodies of the instant invention have different binding affinity is not in dispute, it is the correlation of the actual method steps to the preamble of the claim that is in question. Measuring the interaction between the polyglutamine expansion protein and the antibody will not provide any insight between the interaction of the polyglutamine protein binding to its unknown and undisclosed putative cellular receptor.

There is no correlation in the prior art or the instant specification which would indicate that a compound that interferes with the antibody binding to the polyglutamine expansion of Huntington would interfere with the binding of the polyglutamine expansion protein to the normal cellular target. A compound that interferes with the antibody binding to the polyglutamine expansion protein can act on the antibody alone or it can bind to the polyglutamine expansion protein. However, the instantly claimed method cannot determine to which protein the agents binds, therefore, the claimed method cannot determine if the agent is capable of modulating the interaction between the polyglutamine expansion protein and the cellular target.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 4/16/04